PATENT



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CERTIFICATE OF MAILING & TRANSMISSION

I hereby certify that on AUGUST Q, 2004, which is the date I am signing this certificate, I am depositing this correspondence the United States Postal Service, first class mail, in an envelope addressed to Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450. I further certify that on Million, which is the date I am signing this certificate, I am transmitting this summary via facsimile to Art Unit 1645 at (703) 872-9306, known to me to be the facsimile number of Art Unit 1645 and to Examiner Ford at (571) 273-0857, the facsimile number of Examiner Vanessa L. Ford. A copy of the confirmation being kept for recordkeeping purposes.

Jessica Brøyen

Applicant: TING, Kang Serial No.: 09/412,297 Filed: October 5, 1999 Title: NELL-1 ENHANCED BONE MINERALIZATION Atty. Docket No. 38586-329 Examiner: FORD, Vanessa L. Group Art Unit: 1645

Confirmation Number: 9486

Mail Stop AF Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. § 1.56

Sir:

Pursuant to 37 C.F.R. § 1.56, § 1.97 and § 1.98, Applicant brings the references listed on the attached Form PTO-1449 to the examiner's attention. 37 C.F.R. § 1.56. These references may be material to examination of the above-identified application. Please do not construe the filing of this information disclosure statement as a representation that applicant has made a search (37 C.F.R. § 1.97(g)), or as an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists. We enclose copies of all cited documents (by mail) and all non-patent cited documents (by facsimile).

This Information Disclosure Statement is being submitted:

1. Within three months of the filing date of a national application other than a continued prosecution application under 37 CFR 1.53(d), or within three months of the date of entry of the national stage as set forth in 37 CFR 1.491 in an international application; or before the mailing date of a first Office action on the merits, and therefore, Applicant believes no fee is required;

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	E	2. After the period specified in paragraph (1) hereinabove of this section, but is being filed before the mailing date of either a final action under 37 CFR 1.113, or a notice of allowance under 37 CFR 1.311, or an action that otherwise closes prosecution in the application, and is accompanied by one of the following:					
			(a)	A statement that either:			
				(i)	Each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement;		
				OR			
				(ii)	No item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the statement after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of the information disclosure statement;		
			OR				
☑ (b) The fee in 37 C				in 37 (e of \$180 for filing of an Information Disclosure Statement as set forth C.F.R. 1.17(p).		
			er the	period : issue fe	specified in paragraph (2) of this section, but is filed on or before pay- ee and is accompanied by both:		
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			(b)	The fe	e of \$180.00 for filing of an Information Disclosure Statement as set 37 CFR 1.17(p).		
					ate the Examiner initialing and signing a copy of Form PTO-		
1//0	1449, transmitted herewith, indicating that the information has been considered and made of						
record	herein.						

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the

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cost of such petitions and/or other fees due in connection with the filing of this document to De-

posit Account No. 501946 referencing order number 38586-329.

August <u>2</u>, 2004

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Complete if Known		
Application Number	09/412,297	
	October 5, 1999	
	FORD, Vanessa	
	38586-329	
	Application Number Filing Date First Named Inventor Art Unit Examiner Name	

			U.S. PATEN	T DOCUMENTS	
Examiner	Cite	Document Number Number -Kind Code ² (if known)	Issue Date	Name of Patentee or Applicant of Cited Document	
Initials*	No. '	US-5,674,844	10-07-1997	Kuberasampath et al.	
	2	US-6,083,690	07-04-2000	Harris et al.	
	3	US-6,352,972	03-05-2002	Nimni et al.	
	4	US-6,413,998	07-02-2002	Petrie et al.	
	5	US-6,462,019	10-08-2002	Mundy et al.	

		OTHER PRIOR ART - NONPATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T²
	6	BELLOWS, C.G. et al. "Determination of Numbers of Osteoprogenitors Present in Isolated Fetal Rat Calvaria Cells in Vitro." Dev. Biol. (1989) 133(1), pp. 8-13.	
	7	BURGER, E.H. et al. "Osteoblast and Osteoclast Precursors in Primary Cultures of Calvarial Bone Cells." Anat Rec. 1986 Jan; 214(1): 32-40. Abstract Only.	
	8	HOSHI, K. et al. Fibroblasts of Spinal Ligaments Pathologically Differential Into Chondrocytes Induced by Recombinant Human Bone Morphogenetic Protein-2: Morphological Examinations for Ossification of Spinal Ligaments. Bone Vol. 21, No. 2 (August 1997): 155-162.	
	9	OPPERMAN, L.A. et al. TGF-β1, TGF-β2, and TGF-β3 Exhibit Distinct Patterns of Expression During Cranial Suture Formation and Obliteration In Vivo and In Vitro. Journal of Bone and Mineral Research, Vol. 12, No. 3 (1997): 301-310.	
	10	TAKAGI, K. et al. The reaction of the dura to bone morphogenetic protein (BMP) in repair of skull defects. Ann Surg. Vol. 196, No. 1 (July 1982): 100-109. Abstract only.	
	11	TAKAMI, M. et al. CA ²⁺ -ATPase Inhibitors and Ca ²⁺ -Ionophore Induce Osteoclast-like Cell Formation in the Cocultures of Mouse Bone Marrow Cells and Calvarial Cells. Biochemical and Biophysical Research Communications, Vol. 237, 1997: 111-115. (Article No. RC977090)	
	12	TIEU A. et al. "Identification of Human NEL-2 Associated with Premature Suture Fusion." J Dent Res. 77(A):635, 1998 (Presented March 4-7, 1998, Minneapolis, MN). Abstract Only.	
	13	TING, K. et al. "NEL-2 Expressed in Unitateral Prematurely Fusing and Fused Coronal Sutures." J Dent Res. 77(B):2224, 1998 (In Abstact book, but withdrew from presentation because unable to make June 24-27, 1998 trip to Nice, France). Abstract Only.	
	14	WATANABE, T.K. et al. "Cloning and Characterization of Two Novel Human cDNAs (NELL1 and NELL2) Encoding Proteins with Six EGF-like Repeats." Genomics, Vol. 38, 273-276 (1996).	

Examiner Signature		Date Considered	
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[&]quot;EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. "Applicant's unique citation designation number (optional). "See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. "Enter Office that issued the "Applicant's unique citation designation number (optional). "See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. "Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). "For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. "Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. "Applicant is to place a check mark here if English language Translation is attached."